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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/988,013	11/16/2001	Shui-on Leung	IMMU:014US2	7681

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EXAMINER	
BLANCHARD, DAVID J	

ART UNIT	PAPER NUMBER
1643	

NOTIFICATION DATE	DELIVERY MODE
01/04/2011	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

mail@rkmllp.com

Office Action Summary	Application No.	Applicant(s)	
	09/988,013	LEUNG ET AL.	
	Examiner	Art Unit	
	DAVID J. BLANCHARD	1643	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *30 August 2010*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *28,29,31,32 and 44-47* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *28-29, 31-32 and 44-47* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

1. Claims 1-27, 30 and 33-43 are cancelled.

2. Claims 28-29, 31-32 and 44-47 are pending and under consideration.

Objections/Rejections Withdrawn

3. Applicants' remarks regarding the request for information under CFR 1.105 are acknowledged.

4. The objection to the disclosure at par. [0001] as requiring updating withdrawn in view of the amendments to the specification field 8/30/2010.

Rejections Maintained

Priority

5. The later-filed application must be an application for a patent for an invention which is also disclosed in the prior application (the parent or original nonprovisional application or provisional application). The disclosure of the invention in the parent application and in the later-filed application must be sufficient to comply with the requirements of the first paragraph of 35 U.S.C. 112. See Transco Products, Inc. v. Performance Contracting, Inc., 38 F.3d 551, 32 USPQ2d 1077 (Fed. Cir. 1994).

In view of the decision by the Board of Patent Appeals and Interferences mailed 13 March 2009, the disclosure of the prior-filed application, Application No. 08/289,576, filed August 12, 1994, provides adequate written descriptive support for the claimed invention in the manner provided by the first paragraph of 35 U.S.C. 112. Accordingly, the effective filing date of the instant claims is deemed to be August 12, 1994, the filing date of Application No. 08/289,576.

Claim Rejections - 35 USC § 102

6. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

7. The rejection of claims 28-29, 31-32 and 44-47 under 35 U.S.C. 102(a) as being anticipated by Harris et al (WO 94/09136, published 4/28/1994, cited on PTO-892 mailed 4/23/09) is maintained.

It is noted that Applicant refers to this rejection under section 102(b) in the response and petition filed 8/30/10, however, the instant rejection is applied under section 102(a). Applicant is reminded that declarations under 37 CFR 1.131 may be used to antedate a reference or activity that qualifies as prior art under 35 U.S.C. 102(a) and not under 35 U.S.C. 102(b). See MPEP 715(I).

The reply filed 8/30/2010 again references the previously filed a Rule 131 Declaration (filed 10/23/2009 and 12/28/2009) with evidence showing that applicant had reduced to practice the present invention prior to the effective date of the cited Harris et al reference. The previously field Declaration under 37 CFR 1.131 filed on 10/23/09 and 12/28/2009 under 37 CFR 1.131 has been considered but remain ineffective to overcome the applied reference because the Declaration is not executed by one of the named inventors, e.g., Dr. Shui-On- Leung, and it has not been shown that Dr. Hans Hansen is the sole inventor of the claimed subject matter. MPEP 715.04(I)(B) states:

> An affidavit or declaration by less than all named inventors of an application is accepted where it is shown that less than all named inventors of an application invented the subject matter of the claim or claims under rejection. For example, one of two joint inventors is accepted where it is shown that one of the joint inventors is the sole inventor of the claim or claims under rejection.

To overcome the above deficiency, Applicant has supplied (filed 8/30/10) a petition under 37 CFR 1.183 requesting waiver of the requirement that the declaration be signed by all inventors. In view of the petition decision mailed 12/13/2010, in which applicants' petition was dismissed (see reasons therein), the rejection is maintained.

Thus, the rejection of claims 28-29, 31-32 and 44-47 under 35 U.S.C. 102(a) as being anticipated by Harris et al is maintained.

8. The rejection of claims 44-47 under 35 U.S.C. 102(b) as being anticipated by Adair et al (WO 91/09967, published 7/11/1991, cited on PTO-892 mailed 3/29/10) is maintained.

Adair et al teach a method of designing humanized heavy and light chain variable domain amino acid sequences of murine monoclonal antibody B72.3 comprising comparing the light and heavy chain variable domain sequences of B72.3 with the light and heavy chain sequences of two or more human antibodies (e.g., those in Kabat), wherein the human REI light chain frameworks are selected and the human EU heavy chain frameworks are selected for FR1, FR2 and FR3 and a human consensus heavy chain FR4 was selected and the selected human frameworks are incorporated with the corresponding light and heavy chain CDRs of B72.3 and the light chain mouse residue at position 48 (2 amino acids from CDR2) and the heavy chain mouse residues at position 73, which is close to both CDRs 1 and 3 and could have a detrimental effect on antigen binding were retained in the humanized B72.3 antibody (i.e., residues predicted to have contacts with the CDRs and within a 4.5 Angstrom radius of any atoms within the CDRs). Adair et al also teach preparing the DNA sequences encoding the designed humanized B72.3 light and heavy chain variable domain amino acid sequences, operably incorporating the prepared humanized light and heavy chain variable domain sequences into expression vectors comprising the human light constant region and the human IgG1 constant region, transfecting host cells with the light and heavy chain vectors and culturing the cells under conditions to produce the humanized B72.3 antibody that binds mucin (see entire document, particularly Example 3 and pp. 10-15).

Thus, Adair et al anticipates the claims.

Response to Arguments

The reply filed 8/30/10 states that Adair did not compare to amino acid sequences of the light and heavy chain variable domains with the corresponding amino acid sequences of the light

and heavy chain variable domains of two or more human antibodies and Adair only relates to the development of chimeric antibodies. Applicants' arguments have been fully considered but are not found persuasive. Adair et al at pages 11-12 clearly teaches that the acceptor framework is chosen to maximize/optimize homology with the donor antibody sequences and provides examples of human frameworks to be used, and where the donor antibody is typically a non-human antibody, such as a rodent antibody and the acceptor antibody is a human antibody (page 8, lines 5-7). Further, in example 3, Adair teaches that transfer of the CDRs from mouse to human frameworks might be facilitated if the overall homology between the donor and acceptor frameworks is maximised and comparison of the B72.3 heavy chain sequence with those in Kabat for human heavy chains showed that B72.3 had poor homology for KOL and NEWM, but was very homologous to the heavy chain of EU, which was selected. Thus, the method of Adair clearly teaches comparison between the non-human variable domain sequences and a collection of corresponding human variable domain sequences, e.g., two or more human antibodies, for the selection of appropriate human frameworks. Regarding applicants' argument that that the instant claims require FR4 is from a third human antibody, Adair teaches that FR4 is a consensus human FR4 sequence, which in the absence of the distinguishing structural features, the consensus human FR4 of Adair, which is merely a human FR4 sequence is reasonably interpreted to be a FR4 from a third human antibody, e.g., different from the second human antibody. Additionally, applicants' statement that Adair only relates to development of chimeric antibodies is curious since Adair entitled "Humanised Antibodies" is clearly directed to CDR grafted antibodies in which the non-human CDRs are grafted onto human frameworks, which is by definition a humanised antibody.

At pages 7-8 of the reply, Applicant also states that nothing regarding the Adair "humanized" B72.3 antibody could be found in the literature and there was no data on the purported humanization of B72.3 antibody, including affinity or specificity of a humanized B72.3 antibody. Applicants' arguments have been fully considered but are not found persuasive. As discussed above Adair et al teach the claimed methods of producing a humanized antibody. To the extent that applicant is arguing that Adair et al never produced or tested the humanized B72.3 for antigen binding, applicant is reminded that a prior art reference provides an enabling disclosure and thus anticipates a claimed invention if the reference describes the claimed

invention in sufficient detail to enable a person of ordinary skill in the art to carry out the claimed invention; "proof of efficacy is not required for a prior art reference to be enabling for purposes of anticipation." Impax Labs. Inc. v. Aventis Pharm . Inc., 468 F.3d 1366, 1383, 81 USPQ2d 1001, 1013 (Fed. Cir. 2006). When the reference relied on expressly anticipates or makes obvious all of the elements of the claimed invention, the reference is presumed to be operable. Once such a reference is found, the burden is on applicant to provide facts rebutting the presumption of operability. In re Sasse, 629 F.2d 675, 207 USPQ 107 (CCPA 1980).

For these reasons and those already of record the rejection is maintained.

9. No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to David J. Blanchard whose telephone number is (571) 272-0827. The examiner can normally be reached at Monday through Friday from 8:00 AM to 6:00 PM, with alternate Fridays off. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Misook Yu, can be reached at (571) 272-0839.

The official fax number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/David J. Blanchard/
Primary Examiner, A.U. 1643